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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,107	01/24/2001	Joanne M. Meyer	3322/0H401	5349

7590 11/14/2003

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EXAMINER	
WILDER, CYNTHIA B	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 11/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/770,107	MEYER ET AL.	
	Examin r	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the corr spondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1 136(a) In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1 704(b)

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43 and 54-62* is/are pending in the application.

4a) Of the above claim(s) *21-43,56,59 and 61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20,54,55,57,58,60 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Pri rity under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11/24/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. Applicant amendment filed on July 11, 2003 is acknowledged. Claims 1, 6, 8, 19, 54 and 57 have been amended. Claims 1-43 and 54-62 are pending. Claims 21-43, 56, 59, and 61 are withdrawn from consideration as being drawn to a non-elected invention. All of the amendments and arguments have been thoroughly reviewed and considered but they are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims.

This action is made Final.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejections

3. The claim rejection under 35 U.S.C. 101 directed to claims 1-20, 54, 55, 57, 58, 60 and 62 is maintained and discussed below. The claim rejection under 35 U.S.C. 112 first paragraph directed to claims 1-20, 54, 55, 57, 58, 60 and 62 is maintained and discussed below. The claim rejection under 35 U.S.C. 112 second paragraph directed to claims 1-20, 54, 55, 57, 58, 60 and 62 is withdrawn in view of Applicant's amendments.

Claim Rejections - 35 USC § 101

4. Once again, claims 1-20, 54, 55, 57, 58, 60-62 have been reviewed in light of the Utility Examination 4. Guidelines and Guidelines for Examination of Patent Application under 35 U.S.C. 112, first paragraph, "Written Description" requirement, Federal Register, Vol. 66, No. 4, pages 1092- 1111, Friday, January 5, 2001. Once again, claims 1-20, 54, 55, 57, 58, 60-62 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not

being supported by either specific and/or substantial utility or a well established utility. The claimed isolated nucleic acid and kit which comprises a nucleotide sequence of a polymorphic region of a DISC 1 allelic variant, wherein the DISC 1 allelic variant has a nucleotide sequence that differs from a reference nucleotide sequence selected from the group consisting of: (a) a nucleotide sequence set forth in SEQ ID NO: l; (b) a DISC 1 nucleotide sequence contained in the clone RPI 1 -1 7144, RP1 1-9801, RP4-58N17, 11145-865N13 or RP4-730B 1 3 and the nucleotide and (c) the nucleotide sequence set forth in SEQ ID NO: 4 or wherein the nucleic acid is selected from the group consisting of SEQ ID NOS: 33-43 and complementary sequences thereof is not supported by a specific asserted utility because the disclosed use of the isolated nucleic acid molecule is not specific and is generally applicable to any nucleic acid molecule. For example, the specification at beginning at page 42 disclose the isolated nucleic acid molecule as useful as probes in hybridization reactions or primers in an amplification reaction to specifically identify variant forms of a gene, such as the genes recited in Table 5. These are all non-specific uses that are applicable to nucleic acids in general and are not particular or specific to the nucleic acids claimed. The claimed invention is not supported by a substantial utility because no substantial utility has been established for the claimed isolated nucleic acid molecule or gene product. For example, the specification teaches that the isolated nucleic acid is used as a probe to specifically identify allelic variant forms of a gene; specifically allelic variant of DISC 1 and D1SC2 genes, such as those recited in Table 5 at page 113 of the specification. The specification states that the variant forms of a gene as listed in the cited Table 5 correlate with the presence of a neuropsychiatric disorder, such as schizophrenia, schizo-affective disorder, bipolar affective disorder, unipolar affective, and adolescent conduct disorder. The specification,

however fails to provide any evidence that the claimed allelic variances identified are associated with any neuropsychiatric disorders. The specification appears to only speculate that the claimed allelic variants of the DISC 1 gene are functional, since the DISC 1 gene (from which the allelic variants have been isolated) is known to be associated with neuropsychiatric disorders. Hence, the need for further research is clearly necessary to determine the function of the claimed allelic variants as correlated with a neuropsychiatric disorder or a substantial utility. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case the claimed isolated nucleic acid molecule does not have an asserted or identified specific and substantial utilities or the claimed variant being identified by the probe or primers of the instant invention. Identifying and studying the properties of a gene itself or the mechanisms in which the gene is involved does not define a "real world" context of use. In fact it appears that the claim invention is only useful for identifying itself. Similarly, the claimed use of identifying probes and primers to detect allelic variants of the gene with no asserted function is neither substantial nor specific due to being generic in nature and applicable to a myriad of nucleic molecules. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed.

Claims 1, 7-26 are also rejected under 35 U.S.C. 1 12, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Applicant's Traversal

5. Applicant traverses the rejection on the following ground: Applicant summarizes the rejection made by the Examiner and respectfully disagrees. Applicant states that the claimed invention has specific utility under 35 U.S.C. 101. Applicant states that MPEP 2107.01 states that "a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or " a chromosome marker" would not be considered to be specific *in the absence of a disclosure of a specific DNA target*". Applicant states that in the specification, the DNA target are the specific variants of the DISC1 gene disclosed in Table 5B. Applicant states that since the claimed isolated nucleic acid and kit, which comprises a nucleotide sequence of a polymorphic region of a DISC1 allelic variant, can be used as a gene probe or a chromosome marker for variants disclosed in Table 5, the claimed invention has specific utility. Applicant states that the Examiner contends that the claimed invention is not supported by a substantial utility because no substantial utility has been established for the claimed isolated nucleic acid molecule or gene product. Applicant summarizes the Examiner's rejection and state that the claimed invention actually has substantial utility in several applications that are described in the application as filed. Applicant quotes MPEP 2107.03 and states that the DISC1/DISC2 polymorphisms of the present invention are all ones that were isolated for a population of individuals having a high presence of schizophrenia among family members. Applicant states that hence, contrary to what is stated in the Office action, there is reasonable correlation between the claimed allelic variances and neuropsychiatric disorders. Applicant states that hence, the claimed invention does have specific and substantial utility in prognostic and diagnostic assays as well in therapeutic applications as supported by the specification. Applicant contends that the present application

additionally explains that knowledge of the identify of the allele of one or more DISC1 or DISC2 gene polymorphic regions in an individual, alone or in conjunction with information on other genetic defects contributing to the same disease also allows a customization of the therapy for a particular disease to the individuals' genetic profile. Finally, Applicant contends that the identification of different alleles of DISC1 or DISC2 is also useful for identifying an individual among other individual from the same species, as described by the specification. Applicant contends that the DISC1/DISC2 polymorphisms of this invention additionally have substantial utility in forensic applications and paternity testing.

Regarding the corresponding 112 first paragraph rejection, Applicant argues that the rejection should be withdrawn because the claimed nucleic acid actually do have both specific and substantial utility as explained in detail, *supra*. Applicant concludes that the rejection should be withdrawn since a skill artisan will be able to use the invention in the applications discussed herein.

Examiner's Response

6. The Examiner's acknowledges Applicant's arguments. However, Applicant's response filed on July 11, 2003 is not found persuasive for the following reasons. In regards to Applicant's arguments that the claimed invention is supported by a specific and substantial utility in prognostic and diagnostic assays as well in therapeutic applications as shown in the specification, it is noted that the specification does not provide objective evidence to substantiate functionally of any of the variant nucleic acid sequence (polymorphisms) or fragment comprising the variant nucleic acid sequences to schizophrenia or any other neuropsychiatric disorders. There is no evidence provided in the specification that the claimed variant polymorphisms are

capable of use as a diagnostic, prognostic or therapeutic tool. Likewise, as noted in the prior office action, it cannot be determined that the variant form(s) of the gene as listed in Table 5 is correlated to the presence of a neuropsychiatric disorder. It appears from the specification that Applicant has *only* cited general utilities for the claimed variant sequences as markers for schizophrenia and neuropsychiatric disorders since theses variant sequences were isolated from the DISC1 gene. As noted in the prior office action, further research is clearly required to determine the function of the claimed allelic variants as correlated with a neuropsychiatric disorder or a substantial utility. In light of the discussion above, Applicant has not provided sufficient evidence to overcome the claimed rejection under 35 USC 101. Accordingly, this rejection is maintained.

Regarding the Applicant arguments concerning the rejection under 35 USC 112 first paragraph, it is noted that the rejection is maintained in light of the discussion above concerning the lack of utility for the claimed invention under 35 USC 101. Since Applicant has not established a substantial utility for the claimed variant nucleic acid sequences of the instant invention, it would not be apparent to one of skill in the art how to the variant sequences. Accordingly, the rejection under 35 USC 112 first paragraph is maintained.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

Cynthia B. Wilder, Ph.D.
Examiner
Art Unit 1637

November 10, 2003

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
11/12/03